K132296

JAN - 7 2014

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Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	November 26, 2013
Contact Person and Address:	Martin Ostmann Regulatory Affairs Specialist T 901-399-1809 F 901-566-7080
Name of Device:	Smith & Nephew, Inc. D-RAD SMART PACK
Common Name:	Bone Plates and Bone Screws
Device Classification Name and Reference:	21 CFR 888.3030, single/multiple component metallic bone fixation appliances and accessories – Class II 21 CFR 888.3040, smooth or threaded metallic bone fixation fastener – Class II
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HRS; HWC

Device Description
The D-RAD SMART PACK is a cost-effective sterile procedural kit that contains an anatomically contoured volar distal radius plate and single-use instruments to treat extra-articular and intra-articular distal radius fractures. The Kit consists of an anatomically shaped distal radius fixation plate, associated locking and non-locking screws and pegs, and instrumentation to assist in implantation of the fixation construct.

Intended Use
The D-RAD SMART PACK is intended for the fixation of fractures involving the distal radius.

Technological Characteristics
The construct consist of anatomically shaped plate which used Peri-Loc VLP screw locking technology. Single use instrumentation is contained in the kit which aides in size selection and implantation of the fixation construct. Mechanical testing and analysis has been conducted on the devices to ensure that they meet or exceed predicate standards in terms of fatigue, material strength, and biocompatibility.

Substantial Equivalence Information
The subject devices are identical in function, intended use, indications for use, and material composition with respect to their function to treat fractures of the distal

radius, and very similar in overall design to the predicate devices listed in **Table 1** below.

Table 1: Substantially Equivalent Predicates to the D-RAD SMART PACK

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Bone Plate System	K993106	12/9/99
Smith & Nephew, Inc.	Peri-Loc VDR	K051735	7/19/05
Smith & Nephew, Inc.	Peri-Loc Bone Plating System	K083032	1/7/09

Conclusion

The subject implants and instruments of this 510(k) are identical to the predicates in their indications for use for the distal radius. Furthermore, the subject devices are similar in materials, processing, design, and intended use to the predicate devices listed in **Table 1.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 7, 2014

Smith & Nephew, Incorporated
Mr. Martin Ostmann
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K132296
Trade/Device Name: Distal Radius Fracture Kit (D-RAD SMART PACK)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 27, 2013
Received: November 29, 2013

Dear Mr. Ostmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21

CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): __K132296_____

Device Name: Distal Radius Fracture Kit (D-RAD SMART PACK)

Indications for Use:

The D-RAD SMART PACK is intended for the fixation of fractures involving the distal radius.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices